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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	41

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/030,606	XU ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,35 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 23-24, 35-36 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims 23-24, 35-36 are rejected under 35 USC 112, first paragraph.

Claims 23-24, 35-36 are drawn to method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO:110, wherein the oligonucleotide primers "comprises" at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO:110.

Claims 23-24, 35-36 encompass a method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, using as primers at least two oligonucleotides with unknown structure that share at least 10

nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, for example, oligonucleotides with 100 nucleotides having 10 nucleotides in the middle in common with nucleotide residues 1341-2694 of SEQ ID NO:110, which would be expected to hybridize to a whole universe of nucleic acid species, including those that have little or no structural identity to SEQ ID NO:110.

In other words, claims 23-24, 35-36 encompass a method for determining prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, using numerous structural oligonucleotide variants.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that

> distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of oligonucleotide primers, per Lilly by structurally describing a representative number of oligonucleotide primers or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe oligonucleotide primers in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of, nor any physical or chemical characteristics of any oligonucleotide primers, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses the full length sequence of SEQ ID NO:110, this does not provide a description of the oligonucleotides used in the claimed method that would satisfy the standard set out in Enzo.

The specification also fails to describe the oligonucleotides by the test set out in Lilly. The specification describes only a single full length of SEQ ID NO:110. Therefore,

it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Since the specification fails to adequately describe the product for use in the claimed method, it also fails to adequately describe the claimed method using said product.

Thus, the specification does not provide an adequate written description of a method for method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO:110, wherein the oligonucleotide primers "comprises" at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO:110, that is required to practice the claimed invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO:110, wherein the oligonucleotide primers amplify residues 1341-2694 of SEQ ID NO:110, and wherein the oligonucleotide primers

consists of at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complete complements of nucleotide residues 1341-2694 of SEQ ID NO:110, **does not reasonably provide enablement for a method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO:110, wherein the oligonucleotide primers "comprises" at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO:110**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 23-24, 35-36 are drawn to method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, comprising contacting said sample with at least two oligonucleotide primers specific for nucleotide residues 1341-2694 of SEQ ID NO:110, wherein the oligonucleotide primers "comprises" at least about 10 contiguous nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, or full length complements of nucleotide residues 1341-2694 of SEQ ID NO:110.

Claims 23-24, 35-36 encompass a method for detecting prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, using as primers at least two oligonucleotides with unknown structure, and any length, provided

said oligonucleotides share at least 10 nucleotides of nucleotide residues 1341-2694 of SEQ ID NO:110, wherein the mismatches can be at any positions of the oligonucleotides, for example, oligonucleotides having 10 nucleotides in the middle in common with nucleotide residues 1341-2694 of SEQ ID NO:110. One would expect that the mispaired sequences would hybridize to a whole universe of nucleic acid species, including those that have little or no structural identity to SEQ ID NO:110, because one would expect that when the oligonucleotide is more than 20 nucleotides long, many mismatches are likely to be stable under the conventional conditions used for hybridization, resulting in hybridizing many genes of non-interest (Sambrook et al, eds, 1989, Molecular cloning, a Laboratory manual, 2nd ed, Cold Spring Harbor Laboratoy Press, Cold Spring Harbor, p.11.8, last paragraph, last 17 lines).

In other words, claims 23-24, 35-36 encompass a method for determining prostate cancer or determining expression of SEQ ID NO:110 in a sample of blood or semen, using numerous structural oligonucleotide variants.

The specification does not disclose how to make numerous oligonucleotide variants for use in the claimed method, such that SEQ ID NO:110 could be detected.

One cannot extrapolate the teaching in the specification to the scope of the claim. One would not know how to make the oligonucleotide variants such that SEQ ID NO:110 is detected using said oligonucleotides, in view of a lack of a teaching of how to make said structural oligonucleotide variants. Further, one would expect that using the oligonucleotides encompassed in the claim, unrelated sequences would be detected, because the oligonucleotides are not specific for SEQ ID NO:110 and would be

misprimed, permitting hybridization of unrelated sequence, in view of the above teaching of Sambrook et al.

When given the broadest reasonable interpretation, the oligonucleotides in the claimed method would hybridize to unrelated sequence, and thus the claimed method would be non-specific and would detect unrelated sequences.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

February 24, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER